UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/376,430	08/18/1999	PAUL A. MOORE	PF466P1	6501

22195 7590 04/09/2002

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	26

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/376,430	MOORE ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Prosecution Application

1. The request filed on Jan. 25, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) is acceptable and a CPA has been established. An action on the CPA follows.

Status of Claims

2. Claims 24-102 are pending in the instant application. Claim 102 has been added as requested by Applicant in Paper Number 25, filed Jan. 25, 2002.

Claim Rejections - 35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 24-102 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Claims 24-102 are directed to the protein of SEQ ID NO: 2, identified as a putative receptor molecule of the interleukin common gamma chain family, identified as Cytokine Receptor Common Gamma Chain Like or CRCGCL protein, based on homology to the cytokine receptor family and other common gamma chains. The closest homology is to the Bos taurus common gamma chain of IL-2 receptor, with which it has 7.9% overall similarity and 27.5% local similarity over a stretch of 254 amino acids. Although the evidence is supportive of this protein being a receptor of this family, the protein does not have any specific and substantial utility, or a

well established utility, as determined according to the current Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001.

The instant specification describes the uses and methods of the polypeptide and polynucleotide encoding the polypeptide, and states that the polypeptides can be used in methods such as the generation of antibodies, tissue typing, uses in assays to determine biological function of the protein and to identify ligands which may bind to it and use as a molecular weight marker, and the nucleic acids can be used in chromosome mapping, library screening, forensic methods and tissue typing. However, these are not considered to be specific or substantial utilities for either the protein or the nucleic acid molecules encoding it. The utilities described above are general and would apply to any protein or polynucleotide. The use of a protein to discover its properties and activities does not constitute a specific, substantial utility.

Because the clone was isolated from an activated T-cell cDNA library and Northern analysis showed that CRCGCL is expressed in HeLa cells, a lung carcinoma cell line, the lymph node and spleen tissues, it is asserted that CRCGCL could be important as a cytokine receptor and may regulate the differentiation and/or proliferation of cells, activate proliferation or differentiation of immune cells, increase proliferation or differentiation of hematopoietic cells and modulate hemostatic activity and inflammation. The tissue distribution of this gene in cells of the immune system suggests that the protein product of this clone would be useful for treatment, prophylaxis and diagnosis of various immune and autoimmune diseases which are listed on pages 10-11 and 97-106.

However, the assertion that the protein and/or nucleic acids of the instant invention can

be used in the diagnosis or treatment of diseases or disorders is also not a specific and substantial utility, and is based on both the tissue expression of CRCGCL and the assumption that the protein is a receptor in the cytokine receptor family, which as a family are involved in myriad biological pathways and activities and disorders. Many proteins are members of evolutionarily related families, yet have diverse biological activities and functions. The members of the cytokine receptor family bind distinct ligands and have specific biological activities. There was no ligand known to bind CRCGCL and activate the protein, and the biological activities upon ligand binding were also not known for this protein at the time of filing. It is noted that Applicants have provided a declaration, file July 26, 2001, Paper No. 18, which Applicants assert affirms the predicted use of CRCGCL in immune cell regulation by binding a cytokine, TSLP, and activating the Jak-STAT signal transduction pathway. However, the declaration is not a substitute for information not disclosed in the specification as filed, and is not commensurate with the scope of the claims. The specification did not envison a specific cytokine to which CRCGCL would bind, and did not teach that the cytokine TSLP would bind to the receptor.

There is no nexus between any of the diseases or disorders and the molecules of the instant invention. A stated belief that a correlation exists between the polypeptides and any number of diseases is not sufficient guidance to use the claimed polypeptides to treat and/or diagnose a particular disease; it merely defines a starting point for further research and investigation. The instant application has failed to provide guidance as to how one of skill in the art could use the claimed invention in a way that constitutes a specific or substantial utility. The proposed uses of the claimed invention are simply starting points for further research and investigation into potential practical uses of the claimed protein. Given no disease state or any

other function or activity known for the protein, the protein is not considered to have utility. In Brenner v. Manson, 148 U.S.P.Q. 689 (Sus. Ct,.1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to a protein which has undetermined function or biological significance, and the use of an orphan receptor to discover its ligand or properties does not constitute a specific, substantial utility. All of the biological activities of a protein need not be known to obtain a patent, but there must be some specific and substantial activity or function known. It is possible that after further characterization, this protein might be found to have a patentable utility, such as association with a specific disease. This further characterization, however, is part of the act of invention, and until it has been undertaken the Applicants' claimed invention is incomplete. Because there is no specific and substantial utility asserted, credibility cannot be assessed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4.1 Claims 24-101 remain rejected and new claim 102 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Even if the specification were fully enabling for the above activities and uses of CRCGCL protein, enablement would not be found to be commensurate in scope with the claims. The skilled artisan would not know what functions or activities polypeptides that are 90-95% identical to the polypeptides disclosed in the specification would retain, or polypeptides that can have from one to 30 amino acid substitutions to those polypeptides, or for polypeptides comprising a polypeptide consisting of the amino acid sequence of SEQ ID NO:2 in which 1 or more amino acid residues are substituted, deleted or added, in any combination, and wherein said polypeptide binds an antibody specific for the polypeptide of SEQ ID NO:2.

4.2 Claims 40-102 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification describes a polypeptide sequence consisting of SEQ ID NO: 2. However, the claims as written include polypeptides comprising fragments and homologues, encompass polypeptides that vary substantially in length and also in amino acid composition. The instant disclosure of a single polypeptide, that of SEQ ID NO: 2 with the instantly disclosed specific activities, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of*

California v Eli Lilly & Co, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id at 1170, 25 USPQ2d at 1606."

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, a single isolated polypeptide sequence SEQ ID NO: 2. Given the unpredictability of homology comparisons, and the fact that the specification fails to provide objective evidence that the additional sequences are indeed species of the claimed genus it cannot be established that a representative number of

species have been disclosed to support the genus claim. There is no correlation or nexus provided between possession of the structural features claimed and the encompassed functional features of SEQ ID NO: 2 such that it is clearly conveyed that possession of any polypeptide having this structural region in common would possess the same functional features. For example, claim 40 encompasses a polypeptide that may comprise just seven contiguous amino acids of SEQ ID NO: 2. There is no description of the amino acid sequences that may comprise the rest of the polypeptide. As another example, claim 102 encompasses an isolated protein comprising a polypeptide consisting of amino acid residues 1-371 of SEQ ID NO: 2, which 1 or more amino acid residues are substituted, deleted or added, in any combination, in wherein said polypeptide binds an antibody specific for the polypeptide of SEQ ID NO: 2. This would encompass a protein having a completely different amino acid sequence from the protein of SEQ ID NO: 2 which could be a mimeotope, which could still bind an antibody that is specific for the polypeptide of SEQ ID NO: 2. Further, even if the sequences were definitive of a genus with a specified function, the instantly claimed genus is not so limited and the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the polypeptides encompassed.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600